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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,088	12/27/2005	Richard James Lewis	16096	9222

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SCULLY, SCOTT, MURPHY & PRESSER, P.C.
400 GARDEN CITY PLAZA
SUITE 300
GARDEN CITY, NY 11530

EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
07/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,088	LEWIS ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28,31,33-35 and 37-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-28,31,33-35 and 37-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants' election with traverse of Group 2, claims 1, 5, 6, 12-13, 23, 27, 28, 38-41, 43, 45, 47 and 49, in the reply filed on June 11, 2007 is acknowledged. Applicants' elections of pyroglutamate, absent amino acid, G and V as Xaa1-4, respectively, are also acknowledged. Claims 2-4, 7-11, 14-22, 24-26, 31, 33-35, 37, 42, 44, 46, 48 and 50-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim.

Upon reconsideration of the claims, it has been determined that further restriction of Group 2 is required, because this group encompasses four sets of claims that cannot be searched together, each one requiring a separate and distinct search. As discussed in the previous Office action (and due to a very substantial backlog of new cases at the searching facility and with each examiner), only one polypeptide or one polynucleotide will be searched and examined in each case.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. New group numbers are used below to avoid confusion with the previous Office action.

Group 208, claim(s) 1, 5, 6, 12-13, 23, 27, 28, 38-41, 43, 45, 47 and 49, drawn to the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 5 in which Xaa5 and Xaa6 are any amino acid but C.

Group 209, claim(s) 1, 5, 6, 12-13, 23, 27, 28, 38-41, 43, 45, 47 and 49, drawn to the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 5 in which Xaa5 is any amino acid but C and Xaa6 is absent, or in which Xaa5 is absent and Xaa6 is any amino acid but C.

Group 210, claim(s) 1, 5, 6, 12-13, 23, 27, 28, 38-41, 43, 47 and 49, drawn to the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 5 in which Xaa5 and Xaa6 are absent.

Claims 43, 45, 47 and 49 will be examined or withdrawn in accordance with the group elected.

The specification and claims make it clear that the sequence defined in each group is a separate and distinct sequence. Each of these sequences must be searched separately. The sets of sequences in which one of Xaa5 or Xaa6 is absent and the other one is present may remain together, because these two sets of sequences may be searched together. The terminal three amino acids in each set of sequences are CXC. As discussed above, only one polypeptide will be searched in each application. As previously discussed, because each sequence is different, there is no common technical feature that links the different groups. Therefore, each invention lack unity with the others.

Accordingly, a holding of lack of unity of invention is proper.

As instructed above, Applicants must choose **ONE** polypeptide from among those claimed as indicated in the different groups above. Each polypeptide sequence is a distinct invention requiring separate searches. THESE ARE NOT SPECIES. Each sequence is a chemically, structurally and functionally distinct molecule. Therefore, the each of these polypeptides, and each of the polynucleotides encoding one of the polypeptides, is patentably distinct.

Moreover, each sequence requires a separate set of searches. Applicants should note that searching each sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for <u>one</u> discrete amino acid or nucleic acid sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation and obviousness. Hence, the search for even <u>two</u> different polypeptides in the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Therefore, these inventions are patentably distinct.

Applicants are advised that a reply to this requirement must include an identification of the sequence that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by a complete election.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

In their response to the restriction requirement, Applicants assert that the shared technical feature is enhancing χ-conotoxin activity by modifying the peptide at particular positions. But, Applicants have not indicated which positions at any χ-conotoxin are modified by all of the claimed polypeptides, what the modifications are or how the claimed polypeptides modify the positions of the χ-conotoxins. As a result, Applicants have not demonstrated unity of invention. Moreover, as discussed previously and above, only one polypeptide will be searched in each application as the elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be

traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

rk/2007-06-22

Rosanne Kosson